Alabama Medicaid Agency

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BOB RILEY
Governor

CAROL H. STECKEL, MPH
Commissioner

January 14, 2009

Dear Pharmaceutical Manufacturer:

*****UPDATED CORRESPONDENCE*****

This correspondence is to provide you with formal written notification of an upcoming meeting of the Alabama Medicaid Pharmacy & Therapeutics (P&T) Committee, to be held on **Wednesday, February 11, 2009**. This meeting may involve review of one or more of your company's drug products. Please note: this meeting will be held at the Alabama State Capitol Auditorium located in Montgomery, Alabama and will begin at 9:00 a.m. All meetings of this committee are open to the public.

The following is a list of drug classes for review at this meeting:

Drug Class REVIEWS	
1. Centrally Acting Skeletal Muscle Relaxants – AHFS 122004	6. Selective Serotonin Agonists – AHFS 283228
2. Direct-acting Skeletal Muscle Relaxants – AHFS 122008	7. Antiemetics, Antihistamine – AHFS 562208
3. GABA-derivative Skeletal Muscle Relaxants – AHFS 122012	8. Antiemetics, 5-HT_3 Receptor Antagonists – AHFS 562220
4. Skeletal Muscle Relaxants, Miscellaneous – AHFS 122092	9. Antiemetics, Miscellaneous – AHFS 562292
5. Opiate Agonists and Opiate Partial Agonists – AHFS 280808 and 280812	10. Proton-pump Inhibitors – AHFS 562836

** Please note that a new drug product must be on the market for a minimum of 6 months from launch date in order to be included in a drug class review.*

While we understand there is a level of coordination between members of the manufacturing industry and a provider through the normal course of business, Alabama Medicaid asks manufacturers to respect P&T Committee members' commitment to the State of Alabama by following the procedures available through the P&T policy. Also, as outlined in the P&T Committee Statement of Integrity, Committee members agree not to have ex parte contacts or discussions with manufacturers or representatives whose drugs are presented for review. This is specifically regarding drugs to be reviewed in an upcoming Medicaid P&T meeting.

As you may be aware, manufacturers whose products are scheduled for review are allowed the opportunity to provide written clinical comments for distribution to the Medicaid P&T Committee members prior to the meeting. For products slated for P&T Committee review, manufacturers are also allowed the opportunity to make brief (no more than 5 minutes) oral summary presentations of their products' clinical data to the Medicaid P&T Committee on the day of the meeting. At the initiation of the 5 minute presentation, the speaker will be required to state any financial interest in or other relationship with the manufacturer of any product(s) the speaker intends to discuss. Speakers may not solicit questions from P&T members during the oral presentation. All questions from Medicaid P&T Committee members regarding specific products and/or AHFS drug classes will be addressed by the clinical contractor or Medicaid after the clinical review of the class.

Approval for distribution of written clinical comments to P&T Committee members and approval of oral presentation summary submissions are based strictly upon the following guidelines:

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Written Comments:

1) All written comments must be mailed to Medicaid's Clinical Contractor, *Goold Health Systems (GHS) – Clinical Pharmacy Services, Attn: AL Medicaid P&T Support (1-800-832-9672); 45 Commerce Dr., Suite 5; Augusta, ME 04332*, and received no later than **Wednesday, January 21, 2009**. Packages must be properly labeled "*Attn: AL Medicaid P&T Support*" and include the full contact information (mailing address, phone, fax, and email) of the designated manufacturer's point of contact.
2) Submissions should be limited to one drug product per packet. Manufacturers wishing to provide written comments on more than one drug product must submit a separate packet for each product.
3) **Submissions are limited to 100 pages single-sided (or 50 pages double-sided) and a maximum binder size of 1 inch.** Manufacturers are responsible for ensuring submissions with multiple pages are bound appropriately.
4) Written comments must be confined to evidence-based clinical information and limited to Food and Drug Administration (FDA)-approved indications covered under Alabama Medicaid Pharmacy benefit and not contain anecdotal content.
5) Written comments should be limited to clinical information only and **must not contain any reference to cost or general drug- or disease-specific economic information.**
6) Submissions are limited to hard-copy written form only (not CD-ROM, e-mail, etc.).
7) Manufacturers must provide **twenty (20) copies of written comments** upon submission to *Goold Health Systems* at the above mentioned contact information.

Oral Presentation Summaries:

1) Written notification of your intent to make an oral presentation must be mailed to *Goold Health Systems (GHS) – Clinical Pharmacy Services, Attn: AL Medicaid P&T Support (1-800-832-9672); 45 Commerce Dr., Suite 5; Augusta, ME 04332*, and received no later than **Wednesday, January 21, 2009**. Submissions must be properly labeled "*Attn: AL Medicaid P&T Support*" and include the full contact information (mailing address, phone, fax, and email) of the designated manufacturer's point of contact.
2) Oral presentation summaries should be limited to one drug product per submission. Manufacturers wishing to provide an oral presentation on more than one drug product must submit a separate one-page summary for each product.
3) Oral presentations must also be limited to clinical information only and **must not contain any reference to cost or general drug- or disease-specific economic information.**
4) Oral presentations must be confined to evidence-based clinical information and limited to Food and Drug Administration (FDA)-approved indications covered under Alabama Medicaid Pharmacy benefit and not contain anecdotal content. All statistics identified for discussion must be supported by noting the source from which the information was obtained. This information does not have to be in formal reference form.
5) Submissions are limited to hard-copy written form only (not CD-ROM, e-mail, etc.) and should be clearly labeled as "Oral Presentation Summary".
6) **One (1) copy of a one-page summary** of the material to be presented must be received along with the written notification. (Please note: the presentation summary must be a single-sided document; references, package inserts, and any other information may be submitted but only the summary will be reviewed).

Failure to abide by all of these requirements upon submission will result in a rejection of the clinical comments and/or oral presentation summaries in their entirety. Manufacturers are also encouraged to submit information as soon as possible. Waiting until just days prior to the deadline for submission of these materials may not allow time for corrections and resubmission prior to the deadline. No submissions or resubmissions will be accepted after the designated deadline. At no time should representatives of the pharmaceutical manufacturing entity contact the Clinical Support Contractor, GHS, regarding this submission process. All inquires should be directed to the contact person listed below. Also, please refer to the Medicaid website (www.medicaid.alabama.gov) for additional information related to presentations, timelines, clinical comment submissions, and/or submission of volume discounts. Volume discount submissions should not be included in this submission to GHS, as these will not be reviewed by GHS nor forwarded to Alabama Medicaid. If you should have additional questions regarding this notice or if you have received this letter and are no longer the appropriate contact, please notify the Medicaid Pharmacy Program at (334) 353-4582.

Sincerely,

Bakeba R. Thomas, Administrator
Pharmacy Clinical Support Unit